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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,616	01/22/2004	Luisa Hernandez-Ramirez	91349	5023

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,616	HERNANDEZ-RAMIREZ ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,13 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,13 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 12/04/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 5, 6, 18, 20, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment proposes to add the new limitation, "consisting essentially of", but there is insufficient support for this limitation and is, therefore, considered to introduce new matter. (The term does not appear to be originally disclosed, and the specification never contemplates the exclusion of any particular ingredients, nor provides any criteria for determining when a given component "materially affects" the "basic and novel" characteristics of the invention.

Claim Rejections - 35 USC § 103

Claims 1, 13, 15, 17, 19 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla. **This rejection is maintained.**

As an initial matter, applicant has submitted exhibit I, showing on its face a publication date of 2008, yet having a copyright date of 2000. Applicant has thus concluded that the copyright notice is not the publication date for the particular page. The examiner does not find applicant's argument persuasive because exhibit I is not the page of the reference used.

Applicant further notes that the invention formulation is able to obtain fewer adverse affects with a lower dosage, and is able to achieve these less adverse affects while maintaining the same effectiveness. Applicant asserts the lower dosage is critical in achieving this accomplishment. The lower dosage of these ingredients is not taught or suggested in the art of record. Thus, Applicant believes that Claims 1, 13, 15, 17,19 and 21 are patentable over Cipla. Applicant submitted the supplemental amendment, introducing a Declaration from Luisa Hemandez-Ramirez. The Declaration outlines the results of a study of the effectiveness and side effects of the drugs of the invention given at ¾ dosage of known dosage amounts while maintaining a microbiological eradication of 80% compared to 82% at the known dosage.

As regards adverse effects, only one patient reported having sufferance dizziness and 3 complained from episgastralgia, all of which were temporary.

The adverse effects, significantly, were less in Group 2 than in Group 1, as shown in Exhibit A. Applicant conclude from the above described study that it is critical to lower the specific dosage given to a patient to less than 2000mg tinidazole and less than 150mg Fluconazole in the treatment of infection disease of the female reproductive system, in order to decrease the number of adverse reactions.

The Declaration cites Exhibit A, however, the record is unclear with regards to what Exhibit A is. Additionally, it is unclear which group had the recited temporary side effects. More importantly, it would seem that the patients in the Declaration were given dosages of fluconazole (112.5 mg) and tinidazole (1500 mg) **twice** a day. It would appear that since the administered doses amounts are higher than the amounts contained in the Cipla reference, then it is not critical to have lower than 2000mg tinidazole and less than 150mg fluconazole. Accordingly, the arguments are not persuasive.

Claims 2, 3, 5, 18, 20 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla in view of Gillis et al.

Applicant disagrees with the Examiner's application of Gillis and Cipla. First, Cipla teaches the combination of one tablet of Fluconazole (150mg) and two Tinidazole tablets, totaling 2000 mgs. There is no suggestion in Cipla that Applicant's regime of less than 150mg Fluconazoleand less than 2000mg Secnidazole would be effective. Thus there is no motivation for one to be adding a third ingredient to Cipla. Applicant

has amended Claim 2 so the claim recites "consisting essentially of" language. However, since there is no clear statement in the specification outlining the basic and novel characteristic of the invention pursuant to MPEP 2111.03[R3] the language is consistent with "comprising" and will be interpreted as such. Purely in arguendo, the references would still read on the claims' "consisting essentially of" language if interpreted as such because the references only contain antifungal agents. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s). MPEP 2111.03[R3]. In this instance the addition of all antifungal agents together would not materially affect the basic and novel characteristic of the current invention.

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla and Gillis et al., the combination taken in view of USP 5,660,860.

Claim 16 was rejected under 35 U.S.C. 103(a) as being unpatentable over Cipla in view of USP 5,660,860.

These rejections are maintained.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is

(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612